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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,123	10/20/2000	Paul R. Lesch JR.	8066-057	6851

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/692,123

Applicant(s)

LESCH, PAUL R.

Examiner

Kathryn L Thompson

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly submitted claims 18-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 18-22 are drawn to a method of injecting a medicament and not to the apparatus (medicament cartridge) itself.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

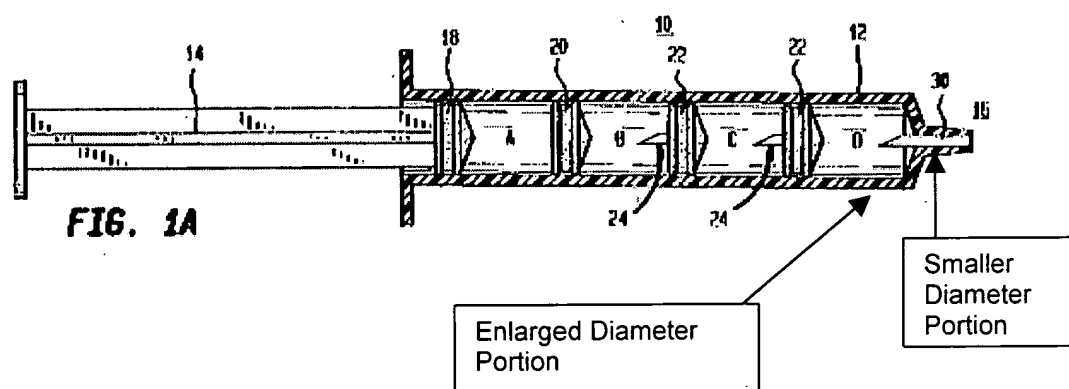
A person shall be entitled to a patent unless –

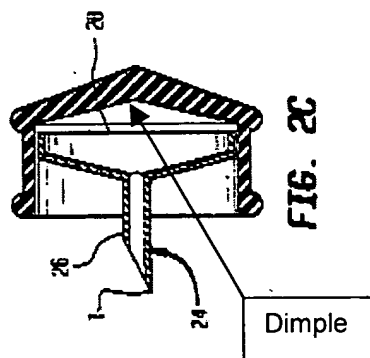
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 6, 7, 9-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Richmond (US 5,102, 388). Richmond discloses a medicament cartridge for an injection system comprising a medicament, a tube, a needle having a piercing end with a bevel extending into the lumen, a first stopper, a second stopper, wherein

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movement of the first stopper with respect to the tube causes the piercing end of the needle to pierce the first stopper and movement of the second stopper with respect to the tube compresses the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway, wherein the lumen has a portion with an enlarged diameter (See Figure 1A Below) and further comprising a third stopper within the lumen located between the second stopper and the enlarged diameter, wherein the first stopper has a frustoconical shape, wherein the second stopper has a medicament contacting surface configured and dimensioned to mate with the frustoconical shape of the first stopper (Figure 2D), wherein the first stopper has a dimple and narrow cross-section where the needle penetrates the first stopper (See Figure 2C Below), wherein the cartridge is configured for use in combination with an injection device (14) for firing the cartridge to expel the medicament.





Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber (US 2,688,967). Huber discloses a medicament cartridge for an injection system comprising a medicament, a tube, a needle having a piercing end with a bevel extending into the lumen and an injecting tip extending beyond the second end of the tube wherein the injecting tip has a bevel, a first stopper, a second stopper, wherein movement of the first stopper with respect to the tube causes the piercing end of the needle to pierce the first stopper and movement of the second stopper with respect to the tube compresses the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway (Figure 5).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond in view of Vetter (US 5, 139, 490). Richmond teaches all of the claimed limitations except a medicament containing insoluble particles. Vetter discloses a medicament containing insoluble particles (Column 3, Lines 22-30). It would have been obvious to one with ordinary skill in the art to combine the teachings of Vetter with the invention of Richmond in order to be able to use the claimed medicament cartridge with lyophilized medicament.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huber in view of Tanaka et al (US 5,605,542). Huber discloses all of the claimed limitations except a portion of the lumen with an enlarged diameter, the third stopper being located between the second stopper and the enlarged diameter portion, wherein movement of the third stopper to the enlarged diameter portion allows the first and second medicament components to mix. Tanaka et al teaches a portion of the lumen with an enlarged diameter (Column 4, Lines 37-41), the third stopper being located between the second stopper and the enlarged diameter portion, wherein movement of the third stopper to the enlarged diameter portion allows the first and second medicament components to mix (Column 5, Lines 24-34). It would have been obvious to one with ordinary skill in the art to use the teachings of Tanaka et al to modify the invention of Huber with an enlarged diameter portion in the lumen in order to create a means for mixing different medicaments.

***Response to Arguments***

Applicant's arguments with respect to claims 1-7 and 11-13 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLT *KdY.*  
February 9, 2003

*Michael J. Hayes*  
MICHAEL J. HAYES  
PRIMARY EXAMINER